UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GREGORY ZAFF AND SONJA CANTU, INDIVIDUALLY, AND AS PARENTS AND NEXT FRIENDS OF THEIR MINOR CHILD, KRISTINA ZAFF, **Plaintiffs,** **v.** **WRIGHT MEDICAL TECHNOLOGY, INC.** **Defendant.**	**Case No. _____**

PLAINTIFFS' COMPLAINT FOR DAMAGES

Plaintiffs GREGORY ZAFF and SONJA CANTU, individually, and as parents and next friends of their minor child, Kristina Zaff, file this Complaint for Damages and Jury Trial Demand against Defendants Wright Medical Technology, Inc., a Delaware corporation whose principal place of business is in Memphis, Shelby County, Tennessee, showing the Court the following:

NATURE OF ACTION

1. For many years, Defendant Wright Medical Technology, Inc. ("Wright," "Wright Medical") has known its hip replacement device – the Wright Medical Profemur® Total Hip System with Profemur® Cobalt Chromium Neck (the "Neck") (collectively referred to as the "Profemur® Total Hip System" or the "Device") – was prone to fretting and corrosion and propensity to fail by fracture of the modular neck-stem junction within a few years of implantation. The Femoral Stem ("Stem") of Wright's Device is comprised of a titanium alloy, while the Neck is comprised of a cobalt chromium alloy. Wright knew the Neck-Stem junction of its Device generates fretting and corrosion in the Neck-Stem body transition, which causes

dangerously elevated levels of CoCr, adverse tissue reactions, pseudotumors, necrosis, bone loss and device failure by fracture at the location of the highest tensile stress in the Neck-Stem body transition. As a result of the Device's defects and Wright's tortious acts/omissions, Plaintiff Gregory Zaff, and many other patients who received these Devices endured unnecessary pain and suffering; debilitating lack of mobility; and a subsequent more difficult revision surgery to replace the defective Device, giving rise to more pain and suffering, a prolonged recovery time, and an increased risk of complications and death from surgery.

JURISDICTION AND VENUE

PARTIES

2. At all relevant times hereto, Plaintiffs Gregory Zaff and Sonja Cantu were and are adult residents and citizens of the State of Massachusetts, residing in Cambridge, Middlesex County, Massachusetts. Plaintiffs were and are the parents of Kristina Zaff.

3. Defendant Wright is a Delaware corporation, with its principal place of business at 1023 Cherry Road, Memphis, Shelby County, Tennessee 38117, and is registered to do business in the State of Tennessee, and at all times relevant hereto did business in the State of Tennessee and in the State of Massachusetts. Defendant Wright is a wholly owned subsidiary of Defendant Wright Medical Group, Inc. Defendant Wright Medical Technology, Inc. is registered to do business in the State of Massachusetts and did business in the State of Massachusetts, including Suffolk County. Wright may be served with process by serving its registered agent for service, Corporation Service Company, at 84 State Street, Boston, Massachusetts 02109, or at Wright's principal place of business at 1023 Cherry Road, Memphis, Tennessee 38117-5423.

4. Wright is a citizen of both the State of Tennessee and the State of Delaware.

5. Defendant Wright was, at all relevant times, engaged in the business of designing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce,

either directly or indirectly through third parties or related entities, various prosthetic orthopedic products, including the Profemur® Total Hip System at issue in this civil action.

6. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000 exclusive of interest and costs and because Plaintiffs and Defendant Wright Medical Technology, Inc. are citizens (or deemed to be citizens) of different states.

7. Defendant Wright is subject to the Court's personal jurisdiction because at all times relevant hereto Defendant transacted business in and continues to transact business in the State of Massachusetts. Defendant has sufficient minimum contacts with Massachusetts such that exercise of jurisdiction over Defendant would not offend traditional notions of fair play and substantial justice.

8. This action arises out of injuries sustained in Massachusetts from a defective product that was marketed, distributed and sold in Massachusetts by Wright. Additionally, the Device at issue was implanted in Plaintiff Gregory Zaff in Massachusetts, the Device failed in Massachusetts, and Plaintiff Gregory Zaff underwent surgery to remove the failed Device in Massachusetts. These contacts are sufficient to confer personal jurisdiction over Defendant pursuant to Massachusetts' long arm statute.

9. Venue is proper in this District pursuant to 28 U.S.C. § 1391 (a) and (b)(2), as a substantial part of the events giving rise to this claim occurred in the Counties of Suffolk and/or Middlesex.

10. At all times relevant hereto, Defendant developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Profemur® Total Hip System, including the cobalt chromium Neck and titanium femoral Stem components, throughout the United States, including Massachusetts.

FACTUAL ALLEGATIONS

11. Profemur® modular necks made of titanium were first patented and marketed by Cremascoli Ortho ("Cremascoli"), a European medical device manufacturer in 1986.

12. In December 1999, Wright acquired Cremascoli, its product lines, documents, and manufacturing facilities, including the Profemur® line of hip products.

13. After the acquisition of Cremascoli, Wright re-designed the Profemur® modular artificial hip stem and modular neck, expanded the product line to include additional titanium models or versions of Profemur® stems and Profemur® modular necks, and rebranded the Cremascoli titanium modular neck product line, and compatible titanium artificial hip stems, as the Wright Profemur® Total Hip System.

14. In making the design change to the PROFEMUR® modular necks, Wright changed the geometry, weight, and mass of the PROFEMUR® modular necks.

15. Sometime after December 13, 2000, Wright began to manufacture, label, market, promote, distribute and sell in the United States the hip implant devices branded as "Profemur® Total Hip System," which included titanium stems and titanium modular necks.

16. Pursuant to the Section 51O(k) Premarket Notification Process ("510(k) Process"), on December 13, 2000, Wright received permission from the United States Food and Drug Administration ("FDA") to distribute in the United States its PROFEMUR Femoral Hip System.

17. The FDA never considered and approved the safety of the PROFEMUR® Total Hip Femoral System, but instead concluded only that the PROFEMUR® was substantially equivalent to an already legally marketed device.

18. The Wright Medical Profemur® modular necks that were distributed by Wright after December 13, 2000, and before August 25, 2009, were all made of the titanium-aluminum-vanadium alloy known as Ti6Al4V.

19. In the year 2000 and in all years thereafter to the present, monoblock hip implant stems without modular neck-stem junctions were readily available in the market.

20. In various marketing and promotional material published and distributed by Wright from approximately the year 2002, and into the year 2005, and available to Wright's sales representatives and distributors, surgeons, patients and the general public, Wright made the following representations, statements, claims and guarantees about its Profemur® modular necks:

> The modular neck used with the Profemur® hip has been employed by Wright Cremascoli for over fifteen years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur® hip. None of the necks has experienced a clinical failure since their inception [emphasis added].
>
> and
>
> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent No. 4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:
>
> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion
>
> [emphasis added].

[Wright Medical Technology Monograph MH688-102© 2004].

21. The representations made by Defendant Wright in the above referenced paragraph regarding the clinical success (i.e. lack of clinical failures) of the Profemur modular neck actually refers to a different device, which was utilized prior to Wright's re-design and rebranding of the product line.

22. Moreover, prior to the year 2001, Wright had received notice of clinical failures in the form of fractures of modular necks that had been implanted in patients in Europe but continued to represent to surgeons that no failures had occurred clinically.

23. In its initial 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright did not disclose to the FDA that it had notice of clinical failures in the form of modular neck fractures that had been implanted in patients in Europe.

24. Once Wright filed its 510(k) Premarket Notification application to distribute its PROFEMUR® modular necks in the United States, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

25. Once Wright began distributing its PROFEMUR® modular necks in the United States, Wright had a duty to report to the FDA any instances it knew, or received notice of, a clinical failure in the form of a fracture of a modular neck that had been implanted in a patient.

26. Prior to April 19, 2005, Wright did not report to the FDA any of the instances it knew or received notice that a PROFEMUR® modular neck had clinically failed by the modular neck having fractured in a patient in Europe.

27. On or about April 19, 2005, Wright for the first time reported to the FDA a Profemur® modular neck clinical failure where a Ti6Al4V modular neck implanted in a patient experienced a catastrophic fracture (i.e., breaking into two pieces) due to fretting and corrosion at the oblong tapered distal end where the neck is seated in the stem.

28. After receiving notice of the 2005 modular neck fracture, Wright received notice of additional modular neck clinical failures from corrosion-based fractures of the modular necks.

29. The number of Profemur® Ti6Al4V modular neck clinical corrosion-based fractures has continued to increase over time, and continues to increase to the present day, now numbering more than 900 such clinical failures.

30. As the number of reported Wright Ti6Al4V modular neck fractures continued to increase, case studies appeared in medical journals reporting the fracture of Wright titanium

Profemur® modular necks and identifying micromotion and fretting corrosion at the neck-stem junction as the cause and mode of failure.

31. At some point in time prior to August 25, 2009, Wright had notice that a higher than normal rate of early failure of its Profemur® line of hip implant devices were failing by fracture at the modular neck junction secondary to micromotion, fretting and corrosion.

32. As the number of reported Wright Ti6Al4V Profemur® modular neck fractures continued to increase, Wright, rather than redesigning its hip implant system to eliminate the modular neck-stem junction and thereby eliminate micromotion and fretting corrosion, instead began to design and develop a Profemur® modular neck made of a cobalt chrome (CoCr) metal alloy utilizing the same taper design and same femoral stems as the titanium modular necks and the same Profemur® stems.

33. On April 16, 2009, Wright submitted a Section 510(k) premarket notification of intent to market a device generally identified as Profemur® hip system modular necks made of a cobalt chrome alloy to the FDA to be coupled with existing Profemur® stems.

34. On or about August 25, 2009, Wright began to market and offer for distribution and sale in the United States Profemur® modular Necks made of cobalt chromium alloy, and Wright simultaneously began withdrawing from the market its Profemur® modular necks comprised of Ti6Al4V titanium alloy.

35. Wright could have eliminated the potential for fretting and corrosion at the modular neck junction of its Profemur® hip implants by abandoning modularity and just market its monoblock stems, but it chose not to do so because Wright did not want to lose its investment in the market share for the use of modular stems in primary hip implant arthroplasties.

36. In promoting its Profemur® CoCr modular Necks Wright claimed that the cobalt chrome modular Necks would result in less fretting than occurred with Ti6Al4V modular necks.

37. The design of the Profemur® CoCr modular Neck, when coupled with the design of the titanium Profemur® hip Stems, is such that it in fact promotes the process of fretting corrosion at the modular Neck-Stem junction.

38. The Profemur® CoCr modular Necks that Wright designed and manufactured were designed to be used with most, if not all, of the same femoral heads and most, if not all, of the same Profemur® titanium hip Stems as were its titanium (Ti6Al4V) Profemur® modular necks.

39. While promoting its Profemur® CoCr modular Necks Wright Medical stated, "[p]roduct complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® CoCr modular Necks." [See Profemur® CoCr Modular Necks Frequently Asked Questions, Wright Medical publication MH 1619-812.]

40. Wright's statement in its promotional materials that "[p]roduct complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® CoCr modular Necks," was not supported by unbiased sound scientific testing.

41. The claim by Wright that "[p]roduct complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® CoCr modular Necks" was false and/or misleading and told to be false by experts retained by Wright.

42. While promoting its Profemur® CoCr modular Necks, Wright claimed that its CoCr modular Necks would result in less fretting than occurred with titanium modular necks.

43. Claims by Wright that its CoCr modular Necks would result in less fretting than occurred with titanium (Ti6Al4V) modular necks were not supported by unbiased, sound scientific testing.

44. Claims by Wright that its CoCr modular Necks would result in less fretting than occurred with titanium (Ti6Al4V) modular necks were false and/or misleading.

45. The design of the Profemur® CoCr modular Neck, when coupled with the design of the titanium (Ti6Al4V) Profemur® hip Stems, is such that it in fact encourages the process of fretting corrosion at the modular Neck-Stem junction.

46. Prior to offering its Profemur® CoCr modular Necks for distribution or sale in the United States, Wright did not adequately test its design of CoCr Profemur® modular Necks for fretting corrosion or fatigue strength.

47. Prior to offering its Profemur® CoCr modular Necks for distribution or sale in the United States, Wright did not adequately test its design of CoCr Profemur® modular Necks for the biological effect of corrosion on the body after implantation in patients.

48. Prior to marketing its Profemur® CoCr modular Necks for distribution or sale in the United States, Wright had independent retained experts opine that changing the makeup of the alloy for Wright's Profemur® modular Necks from titanium to Cobalt and Chromium would not safely address the risk of fracture at the Neck-Stem junction.

49. Wright concealed these opinions and reports from surgeons including Plaintiff Gregory Zaff's surgeon, Dr. Stephen Murphy ("Dr. Murphy"), in order to sell the Profemur CoCr Modular Neck.

50. If Dr. Murphy knew of the aforementioned opinions or received the aforesaid expert reports, Dr. Murphy would not have recommended the Profemur Total Femoral Hip System to Plaintiff Gregory Zaff.

51. If. Dr. Murphy knew of the aforementioned opinions or received the aforesaid expert reports he would have warned Plaintiff Gregory Zaff and/or would not have chosen the Profemur® Total Femoral Hip System for implantation in Plaintiff Gregory Zaff.

52. Defendant had a duty to disclose opinions from its experts concerning risks associated with the Profemur® total femoral hip system to its surgeon customers.

53. As a result of Wright's concealment of its experts' opinions, Plaintiff Gregory Zaff suffered injury.

54. Wright rushed the Profemur® CoCr modular Necks to market without adequately testing it for in vivo performance, including, but not limited to, resistance to fretting, fatigue strength and corrosion or the effects of corrosion on human tissue and ignored the opinions of experts it had hired to study the issue.

55. Wright rushed the Profemur® CoCr modular Necks to market in order to preserve market share and its profits from the sale of its failing Profemur® hip implant products.

56. By June 20, 2013, Wright reached a definitive agreement to sell OrthoRecon, the division of Wright that was responsible for its knee and hip implant products, to MicroPort Medical B.V. ("MicroPort"), and on January 9, 2014, MicroPort acquired OrthoRecon and its franchise brands, including the Device.

57. On August 4, 2015, less than two years after acquiring OrthoRecon and the Device, MicroPort issued a Class 1 device recall for all "PHAC-1254" size LONG, Orientation 8 degree VAR/VAL, 12/14 SLT Taper, Profemur® Plus CoCr Modular Necks.

58. Prior to September 6, 2012, Wright had been informed that it's Profemur® CoCr modular Necks had an unacceptable risk of fracturing at the Neck-Stem junction due to fretting corrosion.

59. Wright knew or should have known that as of September 6, 2012, the date Plaintiff Gregory Zaff received his Wright Profemur® Total Hip System:

(a) Wright had not adequately tested the Profemur® CoCr modular Necks to simulate in vivo performance for resistance to fretting corrosion;

(b) Wright had not adequately tested the Profemur® CoCr modular Necks to simulate in vivo performance for resistance to corrosion;

(c) Wright's Profemur® CoCr modular Necks would be subject to fretting corrosion;

(d) there was an unacceptable risk of fretting corrosion at the Neck-Stem junction;

(e) there was an unacceptable risk of corrosion at the Neck-Stem junction;

(f) there was a substantial risk that patients' bodies would be adversely affected by the exposure to corrosion, metal debris and metal ions secondary to corrosion; and

(g) there was a substantial risk that the Device would catastrophically fail by fracturing at the Neck-Stem body transition during normal use.

60. The Neck-Stem junctions of the Profemur® CoCr modular Neck, coupled with a Profemur® titanium hip stem, are subject to significant movement which results in fretting corrosion, pitting corrosion, and metal ion release.

61. Product complaint data reported to Wright prior to September 6, 2012 indicated an increased risk of adverse events due to taper junction fretting and corrosion for Profemur® CoCr modular Necks when coupled with Profemur® titanium hip Stems, as compared to traditional titanium necks.

62. Based upon what Wright knew or should have known before September 6, 2012, Wright had a duty to orthopedic surgeons using its Profemur® Total Hip Systems that there was an increased risk of fretting, corrosion, and catastrophic fracture of Profemur® CoCr modular Necks when coupled with Profemur® titanium hip stems.

63. The Profemur® CoCr modular Neck, Profemur® titanium modular Stem and the Profemur® Total Hip System are defective in design in that the risks inherent in the product's use for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefit which might have been gained by placing the defective product in the body of Plaintiff Gregory Zaff.

64. Additionally, the Profemur® CoCr modular Neck, Profemur® titanium modular Stem and the Profemur® Total Hip System implanted in Plaintiff Gregory Zaff were defective in manufacture, as Wright manufactured same such that the tolerances between the Stem and Neck components did not comply with Wright's design specifications, such that the device would not experience significant micromotion corrosion or fretting.

65. Based upon the facts and allegations set forth above, the Profemur® CoCr modular neck, Profemur® titanium stem, and the Profemur® Total Hip System are defective in labeling in that they do not perform as represented, and the risks that were inherent in the product being used for hip replacement, when weighed against the utility or benefit derived from the product's use, outweigh any alleged benefit.

66. Based upon the facts and allegations set forth above, the Wright Medical Profemur® CoCr modular neck, Profemur® titanium modular stem, and the Profemur® hip system are unreasonably dangerous in that the risks that were inherent in the product being used for hip replacement, when weighed against the alleged utility or benefit derived from the product's use, outweigh the benefit.

67. Defendant was negligent in its design, manufacture, distribution, sale, marketing, promotion, and labeling of the Profemur® CoCr modular neck, Profemur® titanium modular stem, and the Profemur® Total Hip System.

68. Defendant was negligent in the failure to warn patients and/or surgeons that it had received product complaint data that indicated an unacceptable risk of adverse events due to taper junction fretting and corrosion, as compared to other available safe alternative devices.

69. Defendant was negligent in failing to warn patients and surgeons that it had received product complaint data that indicated an increased risk of adverse events due to corrosion, as compared to other available safe alternative devices.

70. Defendant was negligent in failing to warn patients and surgeons that it had received product complaint data that indicated an increased risk of adverse events due to fracture at the Neck-Stem junction, as compared to other available safe alternative devices.

PLAINTIFF'S INJURIES AND DAMAGES

PLAINTIFF GREGORY ZAFF'S PROFEMUR® HIP

71. On or about September 6, 2012, Plaintiff Gregory Zaff had a Wright artificial hip implanted in his left hip ("Index Surgery") in a procedure known as a total hip arthroplasty (or "THA").

72. Orthopedic surgeon Stephen Murphy, M.D. ("Dr. Murphy") performed the Index Surgery during which he implanted the Profemur® Total Hip System in Plaintiff Gregory Zaff's left hip.

73. Plaintiff Gregory Zaff's Index Surgery was performed at New England Baptist Hospital, 125 Park Hill Avenue, Boston, MA 02120.

74. Dr. Murphy did not breach any generally accepted standards of care in the field of orthopedic surgery in his care and treatment of Plaintiff or negligently cause any injury to Plaintiff in any of the following respects:

(a) in the care or treatment that he provided to Plaintiff Gregory Zaff prior to beginning the hip implant surgery;

(b) in the hip implant surgery, he performed on Plaintiff; or

(c) in the care or treatment that he provided to Plaintiff, subsequent to Plaintiff's hip implant surgery.

75. Based upon the patient population that Wright intended its artificial hip devices to be implanted in (and represented to surgeons, the medical community and the public), at the time of Plaintiff's Index Surgery, Plaintiff Gregory Zaff was an appropriate patient to be implanted with the Profemur® Total Hip System.

76. Dr. Murphy recommended the Profemur® Total Hip System to Plaintiff Gregory Zaff and indicated that the Device was appropriate for him.

77. Plaintiff Gregory Zaff reasonably relied upon Dr. Murphy in deciding to proceed with hip replacement surgery and have the Profemur® Total Hip System implanted.

78. Before or during the course of Plaintiff's Index Surgery, Defendant sold the Profemur® Total Hip System that was implanted in Plaintiff to New England Baptist Hospital and/or Dr. Murphy for implantation in Plaintiff.

79. Defendant, directly or through its subsidiaries or affiliates, designed, manufactured, distributed and sold in the United States various prosthetic orthopedic devices, including the Profemur® Total Hip System implanted in Plaintiff during the Index Surgery, which included the following components:

- Wright Ceramic Femoral Head
  Size 32 mm
  Ref: 2600-0008
  Lot: 1201280044

- Wright Lineage Acetabular Shell
  Size 54 mm
  Ref: 3645-0054
  Lot: 1414868

- Wright Lineage Ceramic Liner
  Size 32 mm
  Ref: 7200-3252
  Lot: 0611372412

- Wright Profemur® Plus CoCr Modular Neck
  Long, 8˚, VAR/VAL
  Model No. PHAC-1254
  Lot: 1419971

- Wright Profemur® Renaissance Femoral Stem
  Model No. PLS0-S414
  Lot: 1404347
  Size: 14

These Wright components are hereinafter, as in prior paragraphs, collectively referred to as the "Profemur® Total Hip System" or the "Device".

80. At the Index Surgery, each of the components of Plaintiff's Profemur® Total Hip System were in substantially the same condition in all relevant respects as when they left Wright's control.

81. At the Index Surgery, each of the components of Plaintiff's Profemur® Total Hip System were in substantially the same condition in all relevant respects as when they left New England Baptist Hospital and/or Dr. Murphy's control.

82. At all times relevant hereto, Plaintiff used the Profemur® Total Hip System implanted during the Index Surgery in a normal and reasonably foreseeable manner.

83. On or about October 25, 2017, the CoCr femoral neck of Plaintiff Gregory Zaff's Device suddenly and catastrophically failed, breaking in pieces at the Neck-Stem junction.

84. On or about October 26, 2017, Plaintiff Gregory Zaff reported to Dr. Murphy, for revision surgery of his failed hip prosthesis ("Revision Surgery").

85. Plaintiff Gregory Zaff's Revision Surgery was necessary because the Device fractured at the Neck-Stem junction.

86. The Revision Surgery was performed by Dr. Murphy at New England Baptist Hospital. During the Revision Surgery, Dr. Murphy removed the failed modular stem of Plaintiff's Profemur® Total Hip System by performing a transfemoral exposure of the natural femur and securing same with cerclage wire.

87. On or about October 26, 2017, the Profemur® Total Hip System implanted in Plaintiff Gregory Zaff's left hip was discovered to have failed as a direct and proximate result of the actions, conduct, negligence, and breach of duties of the Defendants, as alleged in this Complaint.

88. The Profemur® Total Hip System (and its components), to include the Device implanted in Plaintiff was not merchantable and was unreasonably dangerous for its intended and/or reasonably foreseeable uses in that:

(a) it was and is unreasonably dangerous under Massachusetts' law as a result of one or more or a combination of the following:

(i) the Neck was manufactured/designed in such a manner as to be subjected to excessive micromotion and fretting corrosion, thereby increasing the potential for failure;

(ii) the surface of the section of the Neck that was inserted into the modular Stem was manufactured/designed in such a manner as to increase the potential for fretting and corrosion, thereby increasing the potential for failure;

(iii) the portion of the Neck that was inserted into the modular Stem was in a narrow, confined space, thereby increasing the potential for fretting, corrosion and failure;

(iv) the components were manufactured/designed in such a way as to make the modular Neck component susceptible to micromotion, fretting and corrosion, thereby increasing the potential for failure;

(v) the components were manufactured/designed in such a way as to cause dissimilar metals (i.e. a CoCr modular Neck and titanium modular Stem) to mate by insertion into a narrow, confined space, thereby increasing the potential for corrosion; and

(vi) there may be other conditions or defects yet to be determined.

(b) it was dangerous to an extent beyond which could be contemplated by the ordinary consumer with the ordinary knowledge common to the community as to its characteristics in that:

(i) the ordinary consumer would not contemplate that the Device would become so corroded and fracture that premature revision surgery would become necessary approximately only 5 years after implantation; and

(ii) the ordinary consumer would not contemplate that the ordinary activities of daily living would result in the Device fracturing in the consumer's body.

89. The Device was not tested in design and development under conditions that were known would be encountered in the normal in vivo patient environment over substantial periods of time.

90. The Device was not tested for the FDA Section 510(k) Premarket Notification Process under conditions that were known would be encountered in the normal in vivo patient environment.

91. The Device was known by Wright to be at risk for failing from fretting and corrosion of the modular Neck-Stem junction prior to the day of its FDA 510(k) Premarket Notification Application.

92. The Device was known by Defendant to be at risk for failing at higher than expected rates from micromotion, fretting, corrosion, and fracture of the modular Neck-Stem junction prior to the date of its implantation in Plaintiff during the Index Surgery.

93. The Device was known by Defendant to be at risk for failing at higher than expected rates due to fretting, corrosion, and fracture prior to the date of Plaintiff Gregory Zaff's Revision Surgery.

94. Prior to the Index Surgery, Defendant did not warn patients, surgeons, customers, or Wright's representatives/distributors that the Device was known to be at risk for failing from corrosion and fracture at higher than expected rates.

95. On or about October 26, 2017, Plaintiff Gregory Zaff discovered the Device implanted in his left side fractured due to micro-motion, fretting and corrosion as a result of one or more or a combination of the foregoing unreasonably dangerous conditions.

96. As a direct and proximate result of the failure of the Profemur® Total Hip System, Plaintiff Gregory Zaff has sustained injuries and damages, including, but not limited to:

(a) undergoing surgery to remove and replace the failed prosthesis;

(b) past and future pain and anguish, both in mind and in body;

(c) permanent diminishment of his ability to participate in and enjoy the affairs of life;

(d) medical bills associated with the revision surgery and recovery therefrom;

(e) future medical expenses;

(f) loss of enjoyment of life;

(g) loss of past and future earnings and earning capacity;

(h) disfigurement; and

(i) physical impairment.

97. Plaintiff Gregory Zaff's injuries were both factually and proximately caused by the Wright's defective Profemur® Total Hip System.

98. Plaintiffs' injuries were both factually and proximately caused by the Wright's unreasonably dangerous Profemur® Total Hip System.

99. Plaintiffs further show that that they are entitled to recover for all noneconomic and compensatory damages allowed by law, including, but not limited to, all pain and suffering

incurred as a result of the defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as a result of the failure of the Device.

LIABILITY

COUNT 1 – NEGLIGENT DESIGN AND FAILURE TO WARN OR INSTRUCT

100. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

101. Wright owed a duty of reasonable care to the general public, including Plaintiff Gregory Zaff, when it designed, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, and sold the Profemur® CoCr modular Neck, the Wright Profemur® titanium modular Stem, and the Profemur® Total Hip System, to protect users from an unreasonable risk of harm when using the Device for its intended purpose, in a reasonably foreseeable manner.

102. Wright breached this duty by designing, manufacturing, assembling, inspecting, testing, marketing, distributing and selling the Profemur® CoCr modular Neck, the Profemur® titanium modular Stem and the Profemur® Total Hip System in a defective and unreasonably unsafe condition including, but not limited to, its foreseeably appreciated risk of harm from the device's propensity for fretting, corrosion, and catastrophic fracture at the Neck-Stem junction. A reasonably prudent medical device manufacturer would not have acted in this manner.

103. Likewise, Wright owed Plaintiff Gregory Zaff a duty of reasonable care to discover the defects and to inform and/or warn him or his implanting surgeon of the defects once they were discovered, and Wright failed to warn of the dangers inherent in the reasonably foreseeable use of the Profemur® Total Hip System, further placing Plaintiff at risk for harm and injury.

104. Wright failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotion and

distribution of the Profemur® Total Hip System. Wright knew or should have known that these products cause significant bodily harm and were not safe for use by consumers.

105. Wright was negligent in incorporating a cobalt chromium modular Neck and titanium modular Stem for the Neck-Stem junction of the Device.

106. Wright, furthermore, in advertising, marketing, promoting, packaging and selling the Device negligently misrepresented material facts regarding its safety, efficacy, and fitness for human use by claiming the Device was fit for its intended purpose when, in fact, it was not.

107. Wright, in advertising, marketing, promoting, packaging and selling the Device, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the Device had been adequately and reliably tested when, in fact, it had not.

108. Wright, in advertising, marketing, promoting, packaging and selling the Device, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the risk of serious adverse events and/or effects from the Device was comparable to that of other hip replacements systems when, in fact, it was not.

109. Wright, in advertising, marketing, promoting, packaging and selling the Device, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the Device had not caused or contributed to serious adverse events and/or effects requiring the premature revision surgery to replace and/or repair the Device when, in fact, it had.

110. Wright, knew or had reason to know that Plaintiff Gregory Zaff, as a member of the general public for whose use the Device was placed into interstate commerce, would be likely to use the Device in a manner described in this Complaint.

111. Wright knew or should have known of the dangers associated with the manner and circumstances of Plaintiff's foreseeable use of the Device, and that said dangers would not be obvious to the general public.

112. Despite the fact that Wright knew or should have known that the Profemur® Total Hip System posed a serious risk of bodily harm to consumers, Wright continued to manufacture and market the Device for use by consumers.

113. Wright knew or should have known that consumers such as Plaintiff Gregory Zaff would foreseeably suffer injury as a result of Wright's failure to exercise ordinary care as described above.

114. Wright's conduct, as described above, including, but not limited to, its failure to adequately test and warn as well as their continued marketing and distribution of the Profemur® Total Hip System when it knew or should have known of the serious health risks these Devices, was and is negligent.

115. As a direct and proximate result of Wright's negligence, including negligent testing, failure to warn and misrepresentations, Plaintiffs suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future.

116. As a direct and proximate result of Wright's negligence, Plaintiffs suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

117. Wright was negligent in the particulars set forth in this Complaint, and such negligence was a direct and proximate cause of the incident and injuries set forth herein.

COUNT 2 – BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY: DEFECTIVE DESIGN

118. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

119. Plaintiffs seek damages against Defendant pursuant to Mass. Gen. L. ch. 106, § 2-314 which provides, *inter alia*, that goods must be "fit for the ordinary purposes for which

such goods are used" and must "conform to the promises or affirmations of fact made on the container or label if any." Massachusetts Warranty Law is congruent in nearly all respects with the strict liability principles in the Restatement (Second) of Torts 402A (1965).

120. Plaintiff Gregory Zaff was damaged by the defective Profemur® CoCr modular Neck, the Profemur® titanium modular Stem, and the Profemur® Total Hip System.

121. Wright was engaged in the business of manufacturing, selling and distributing the Profemur® CoCr modular Neck, the Profemur® titanium modular Stem, and the Profemur® Total Hip System.

122. Defendant had a duty to design, manufacture, distribute, market, promote and sell, the Profemur® Total Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

123. The Wright Profemur® Total Hip System used in Plaintiff Gregory Zaff's hip replacement surgery was supplied in a defective condition in its design, such that it would experience micromotion, fretting, corrosion and catastrophic fracture at the Neck-Stem juncture, rendering it unreasonably dangerous.

124. Defendant had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the Profemur® Total Hip System so that it was neither defective nor unreasonably dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

125. On and prior to September 6, 2012, Defendant was engaged in the business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Device.

126. Defendant did in fact manufacture, sell, distribute, supply and/or promote the Device to Plaintiff Gregory Zaff and his implanting physician. Defendant expected the Device it was selling, distributing, supplying, manufacturing and/or promoting to reach, and which did in

fact reach, implanting physicians and consumers in the State of Massachusetts, including Plaintiff Gregory Zaff and his implanting physician, without substantial change in the condition.

127. At the time the Device left the possession of Defendant and the time the Device entered the stream of commerce, it was in an unreasonably dangerous and defective condition. These defects include, but are not limited to, the following:

(a) the Device was not reasonably safe as intended to be used;

(b) the Device had a defective design for the purpose of hip replacement;

(c) the Device contained unreasonably dangerous design defects, including an inherently unstable and defective design, to include the use of dissimilar metal alloys (i.e. a CoCr modular Neck and titanium modular Stem) at the Stem and Neck junction, which resulted in an unreasonably high probability of early failure;

(d) the Device's unstable and defective modular design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

(e) the Device was not appropriately or adequately tested before its distribution;

(f) the Device has an unreasonably high propensity for micro-motion, fretting corrosion, and fracture under normal and expected use of the Device; and

(g) the Device was not accompanied with adequate warnings and instructions.

128. At the time of Defendant's design, manufacture, marketing and sale of the Device, a feasible, alternative safer design for the Device was known and available to Defendant, including, but not limited to, a monoblock stem design.

129. At the time of and subsequent to Defendant's design, manufacture, marketing and sale of the Device, including prior to the time of Plaintiff's initial hip implant surgery, Defendant had the ability to eliminate the unsafe character of the Device.

130. Wright's Profemur® Total Hip System device, manufactured and supplied by Defendant, was, therefore, defective in design or formulation in that, when it left the hands of Defendant, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Device's particular design or formulation, and/or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

131. The foreseeable risks associated with the design or formulation of the Profemur® Total Hip System device includes, but is not limited to, the fact that the design or formulation of the Profemur® Total Hip System device is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

132. As a direct and proximate result of Plaintiff's use of Wright's Profemur® Total Hip System device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendant, Plaintiff Gregory Zaff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

133. As a direct and proximate result of Defendant's defective product and tortious conduct as set forth herein, Plaintiff has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

134. The Profemur® Total Hip System's defective condition proximately caused Plaintiffs' damages.

COUNT 3 – BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY: MANUFACTURING DEFECT

135. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

136. At all times relevant hereto, Wright was engaged in the business of manufacturing, selling and distributing the Profemur® CoCr modular Neck, the Profemur® titanium modular Stem, and the Profemur® Total Hip System.

137. The Profemur® Total Hip System purchased by Plaintiff from Wright is a good subject to an implied warranty of merchantability pursuant to Mass. Gen. L. ch. 106, § 2-314, under which Defendant seller impliedly warranted that the goods it provided to Plaintiff were safe, merchantable, and reasonably suited for the ordinary purposes for which the Device was sold.

138. Wright designed, manufactured, assembled and sold the Profemur® Total Hip System device to medical professionals and patients knowing that it would then be implanted in patients in need of a hip prosthesis.

139. Plaintiff Gregory Zaff, a patient in need of a hip prosthesis, was a person whom Defendant-manufacturer Wright reasonably would have expected to use or be affected by the Device when used in a manner that the Wright intended or reasonably could have foreseen.

140. Wright did not effectively disclaim the warranty.

141. The Profemur® Total Hip System used in Plaintiff's hip replacement surgery was supplied in a defective condition in its manufacture, in that the tolerances did not match Wright's specifications, such that it would experience micro-motion, fretting, and corrosion at the Neck-Stem junction, following implantation in Plaintiff's hip. This defect rendered the Profemur® Total Hip System implanted in Plaintiff to be unsuitable for its ordinary use and unreasonably dangerous.

142. The Profemur® Total Hip System device was expected to and did reach Plaintiff and his implanting surgeon, Dr. Murphy, without substantial change or adjustment in its condition as manufactured and sold by Wright.

143. As a direct and proximate result of Wright's breach of its implied warranty of merchantability Plaintiff Gregory Zaff was damaged by the defective Profemur® CoCr modular Neck, the Profemur® titanium modular Stem, and the Profemur® Total Hip System, necessitating surgery to remove the fractured Device.

COUNT 4 – BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY: FAILURE TO WARN

144. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

145. At all times relevant hereto, Defendant was engaged in the business of manufacturing, selling and distributing the Profemur® CoCr modular Neck, the Profemur® titanium modular Stem, and the Profemur® Total Hip System.

146. At all times relevant herein, Defendant was also engaged in the design, development, testing, manufacturing, marketing and sale of the Profemur® Total Hip System device.

147. Defendant designed, manufactured, assembled and sold the Profemur® Total Hip System device to medical professionals and patients knowing that it would then be implanted in patients in need of hip prosthesis.

148. The Profemur® Total Hip System purchased by Plaintiff from Defendant is a good subject to an implied warranty of merchantability pursuant to Mass. Gen. L. ch. 106, § 2-314, under which Defendant impliedly warranted that the goods it provided to Plaintiff were safe, merchantable, and reasonably suited for the ordinary purposes for which the Device was sold.

149. Defendant did not effectively disclaim this warranty.

150. Wright's Profemur® Total Hip System device designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendant was in a dangerous and defective condition and posed a threat to any user or consumer of the Profemur® Total Hip System device.

151. Defendant distributed and sold the Profemur Total Hip System device in a condition such that when it left Defendants' control, in the original form of manufacture, the device included the defects described herein.

152. The Profemur® Total Hip System device was expected to and did reach Plaintiff and his implanting surgeon, Dr. Murphy, without substantial change or adjustment in its condition as manufactured and sold by Defendant.

153. Plaintiff Gregory Zaff was damaged by the defective Profemur® CoCr modular Neck, the Profemur® titanium modular Stem, and the Profemur® Total Hip System.

154. At all times relevant herein, Plaintiff Gregory Zaff was a person whom Defendant should have considered to be subject to the harm caused by the defective nature of the Profemur® Total Hip System device.

155. Wright's Device was implanted and used in the manner for which it was intended.

156. This use has resulted in severe physical and emotional and other injuries to Plaintiffs.

157. Defendant knew or should have known through testing, adverse event reporting or otherwise that its Profemur® Total Hip System device created a high risk of bodily injury and serious harm.

158. Defendant had a duty to warn sales representatives/distributors, implanting surgeons such as Dr. Murphy and patients such as Plaintiff Gregory Zaff, and Defendant breached its duty in failing to provide adequate and timely warnings or instructions regarding their Profemur® Total Hip System devices and their known defects.

159. Defendant, furthermore, breached its duty to warn at pre-surgery and/or post-surgery by (a) failing to adequately communicate the warning to Wright's sales representatives/distributors and/or to the ultimate users, i.e., Plaintiff and/or his implanting physician; and/or (b) by failing to provide an adequate warning of the Device's potential risks.

160. Adequate efforts to communicate a warning to the ultimate users was not made by Defendant (or Wright's sales representatives/distributors) and, to the extent a warning was communicated by Defendant, the warning was inadequate.

161. The warnings (pre-surgery and/or post-surgery) to Plaintiff and his implanting physician about the dangers the Device posed to consumers were inadequate. Examples of the lack and/or inadequacy of Defendant's warnings include, but are not limited to, one or more of the following particulars:

(a) the Device contained warnings insufficient to alert Plaintiff and Plaintiff's physicians as to the unreasonably high failure rate and propensity for corrosion and fracture, associated with the Device, subjecting Plaintiff Gregory Zaff to risks which exceeded the benefits of the Device;

(b) the Device contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with it, thereby making use of the Device more dangerous than the ordinary consumer would expect;

(c) the Device contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with the Device;

(d) the Device did not disclose that it was inadequately tested;

(e) the Device failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by the Device; and

(f) the Device failed to contain instructions sufficient to alert consumers to the dangers it posed and to give them the information necessary to avoid or mitigate those dangers.

162. Plaintiff Gregory Zaff used the Device for its intended purpose, i.e., hip replacement.

163. Plaintiff could not have discovered any defect in the Device through the exercise of due care.

164. Defendants, as designers, manufacturers, marketers and distributors of medical devices are held to the level of knowledge of an expert in the field.

165. Plaintiff and his implanting physician did not have substantially the same knowledge about the Device as Defendant, who was the designer, manufacturer, and/or distributor of the Device.

166. As a direct and proximate result of Defendant's failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, as set forth herein.

167. As a direct result of Defendant's failure to warn and/or inadequate warning and Defendant's other tortious conduct, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

168. As a direct and proximate result of Defendant's failure to warn and/or inadequate warning and Defendant's other tortious conduct, as set forth herein, Plaintiff has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

COUNT 5 – NEGLIGENT MISREPRESENTATION

169. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

170. Wright had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that the Profemur® Total Hip System had not been adequately tested and found to be safe and effective for the treatment of patients requiring a hip replacement. Instead, Wright made representations about the device that it, at a minimum, should have known to be false.

171. Wright negligently misrepresented to the medical community, implanting orthopedic surgeon Dr. Murphy, Plaintiff, and the public that the Profemur® CoCr modular Neck coupled with the Profemur® titanium modular Stem in the Profemur® Total Hip System presented a low risk of unreasonable and dangerous adverse side effects.

172. Additionally, in various marketing and promotional material published and distributed by Wright from approximately the year 2002, and into the year 2005, and available to Wright's sales representatives and distributors, surgeons, patients and the general public, Wright made the following representations, statements, claims and guarantees about its Profemur® modular necks:

> The modular neck system, designed by Cremascoli in 1985 (U.S. Patent #4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:
>
> - Structural reliability

- Absence of significant micromovement
- Absence of fretting corrosion

[e.g., Wright Medical Technical Monograph MH688-102 ©2002, and ©2004]

173. The above quoted statement by Wright that it, "guaranteed . . . absence of fretting corrosion," with its Profemur® modular Necks was false at the time it was first made by Wright.

174. The above quoted statement by Wright that it, "guaranteed . . . absence of fretting corrosion," with its Profemur® modular Necks was false at the time Wright stopped making that statement in its printed publications in the year 2005.

175. Wright has never corrected or recanted its above quoted statement that it "guaranteed . . . absence of fretting corrosion," with its Profemur® modular Necks.

176. Testing done by Wright prior to the year 2003 proved that fretting corrosion occurred with its Profemur® modular Necks.

177. Post market surveillance conducted by Wright from the years 2003 through 2012 proved that fretting corrosion occurred with its Profemur® CoCr modular Necks led to fracturing at the Neck-Stem junction.

178. Testing done by Wright Medical in 2008-2012 proved that fretting, corrosion, and fracture occurred with its Profemur® modular Necks.

179. The design of the taper junction joining the modular neck and stem of the Profemur® Hip System has remained the same since at least 2002.

180. Wright promoted that the design of the junction joining the modular neck and stem of the Profemur® Hip System is the same as to the titanium modular neck and the cobalt chromium modular neck.

181. In various marketing and promotional material published and distributed by Wright Medical from approximately the year 2002, and into the year 2008, and available to Wright's sales representatives and distributors, surgeons, patients and the general public, Wright

made the following representations, statements, claims and guarantees about its Profemur® modular Necks:

> In summary, the clinical effectiveness and dependability of modular necks has been consistently demonstrated throughout the clinical history of Wright's Profemur® modular necks. Utilized in both primary and revision applications, the current neck design has been successfully employed to improve surgical outcomes with no reported failures.

[See: Stature™ Modular Hip Reconstruction – Design Rationale – Your stem philosophy. Your neck choice. Your cup preference. Wright Medical Technology, Inc. publication MH 179-703, Rev 9.08]

182. By the date of May 1, 2005, if not before, Wright knew that the above quoted statement by Wright that, "Utilized in both primary and revision applications, the current neck design has been successfully employed to improve surgical outcomes with no reported failures," was false.

183. Wright has never corrected or recanted its above quoted statement: "Utilized in both primary and revision applications, the current neck design has been successfully employed to improve surgical outcomes with no reported failures."

184. After Wright's titanium Profemur® modular necks began to be implanted, Wright began to receive reports of its Profemur® titanium modular necks having corroded and fractured (i.e., broken into pieces) at the oblong taper distal end where it is seated in the Profemur® stem.

185. Plaintiff and Plaintiff's implant surgeon relied on Wright to accurately and truthfully represent material facts regarding the Device, including its safety and effectiveness and associated risks. Plaintiff Gregory Zaff and Plaintiff's implanting surgeon did not have the ability to independently determine the truth or falsity of Wright's claims through reasonable diligence. Plaintiff and Plaintiff's reliance was reasonable and justified and resulted in Plaintiffs' damages.

186. Had Defendant accurately and truthfully represented to the medical community, Dr. Murphy, Plaintiff, and the public the material facts that it knew or should have known regarding the risks of the Profemur® CoCr modular Neck coupled with the Profemur® titanium

modular Stem as part of the Profemur® Total Hip System, Plaintiff and/or Plaintiff Gregory Zaff's healthcare provider(s) would not have utilized Defendant's Profemur® Total Hip System.

187. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT 6 – FRAUD BY CONCEALMENT

188. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

189. Wright, as manufacturer of the Profemur® Total Hip System, was armed with superior knowledge of the latent dangers associated with the Device (namely corrosion, fretting, and fracture) and had a duty to communicate these dangers to Plaintiff and Plaintiff's implanting surgeon.

190. Wright had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that Wright Medical Profemur CoCr Modular Neck, and the Wright Medical Profemur Total Hip System, had not been adequately tested and found to be safe and effective for the treatment of patients requiring a hip replacement. Instead, Wright knew, but deliberately failed to communicate this to Plaintiff or Plaintiff's surgeon.

191. Wright had a duty to inform, but fraudulently concealed from the medical community, implanting orthopedic surgeon Dr. Murphy, Plaintiff, and the public that the Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem in the Wright Medical Profemur Total Hip System had an unreasonable and dangerous risk of corroding, fracturing, and causing bodily injury.

192. Through the reporting of adverse events to Wright and by reports from experts in metallurgy and biomechanics retained by Wright, Wright knew of the risk of corrosion and subsequent fracture and resulting bodily injury present in the device implanted in Plaintiff but did not disclose this information. Neither Plaintiff nor Plaintiff's surgeon had this information, nor could they have discovered this information through reasonable diligence.

193. Wright had a duty to communicate the increased risk and known failures associated with the device implanted in Plaintiff to Plaintiff and Plaintiff's surgeon.

194. Plaintiff and Plaintiff's surgeon justifiably relied upon Wright to communicate known risks and failures when making both the decision to implant the device and the appropriate course of treatment following Plaintiff's index surgery.

195. Had Wright accurately and truthfully represented to the medical community, Dr. Murphy, Plaintiff, and the public the material facts that it knew regarding the risks of the Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem as part of the Wright Medical Profemur Total Hip System, Plaintiff and/or Plaintiff's healthcare provider(s) would not have utilized Defendant's Profemur Total Hip System.

196. Had Wright not fraudulently concealed the increased risk of corrosion, effects of corrosion, and the known failures of the Device from Plaintiff or Plaintiff's surgeon, Plaintiff's injuries would have been avoided or limited.

197. As a direct and proximate result of Wright's fraudulent concealment, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

198. Pursuant to Mass. Gen. L. ch. 231, §85J, Plaintiffs are entitled to damages in treble the amount of damages sustained.

COUNT 7 – FRAUDULENT MISREPRESENTATION

199. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

200. Wright, as manufacturer of the Profemur® Total Hip System armed with superior knowledge regarding the latent defects and failure rates associated with the Device, had a duty to accurately and truthfully represent to the public, the medical community, Plaintiff, and Plaintiff's surgeon, the material facts that it knew regarding the risks of the Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem as part of the Wright Medical Profemur® Total Hip System.

201. Wright made false representations of material fact to Plaintiff Gregory Zaff and/or his healthcare providers as to the safety and efficacy of the Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular neck in the Wright Medical Profemur Total Hip System. Instead of disclosing the heightened risks of corrosion, fracture, failure, and permanent injury, Wright represented:

a) that there was no indication of an increased risk of adverse events due to taper junction fretting and corrosion;

b) that lab testing guaranteed structural reliability and the absence of significant micromovement and absence of fretting corrosion;

c) that product complaint data did not indicate an increased risk of corrosion for Wright Medical Profemur CoCr Modular Necks when coupled with Wright Medical Profemur titanium hip stems;

d) that, "[u]tilized in both primary and revision applications, the current [Profemur modular] neck design has been successfully employed to improve surgical outcomes with no reported failures";

e) that Profemur® cobalt-chromium modular necks would result in less fretting than occurred with titanium modular necks;

f) that Profemur® cobalt-chromium modular Necks coupled with Profemur® stems showed a total absence of corrosion in an in vivo environment; and

g) that the Wright Medical Profemur Total Hip System, including its component parts, were safe and effective, and were safer and more effective than other treatments for hip replacements.

202. Wright knew that the above representations alleged in paragraph 201 were false, yet Wright willfully, wantonly, and recklessly disregarded the inaccuracies in its representations.

203. Wright made these false representations with the intent of defrauding and deceiving the medical community (including implanting surgeon Dr. Murphy), Plaintiff, and the public, and to induce the medical community, Plaintiff's implanting surgeon, Plaintiff, and the public to utilize its Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem as part of the Profemur Total Hip System. Doing so constituted a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff and the public.

204. Plaintiff and his implanting orthopedic surgeon Dr. Murphy justifiably relied upon Wright's false representations of material fact in deciding to utilize the Wright Medical Profemur Hip System, including the CoCr modular neck and titanium modular stem. Plaintiff and Plaintiff's implanting surgeon, Dr. Murphy, were not in a position to determine the truth or falsity of Wright's representations through reasonable diligence.

205. Had Plaintiff or his healthcare providers known the true facts about the dangers and health risks of the Wright Medical Profemur CoCr Modular Neck coupled with the Wright Medical Profemur titanium modular stem as components of the Wright Medical Profemur Total Hip System, they would not have utilized these products.

206. As a direct and proximate result of Wright's fraudulent conduct, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

207. Pursuant to Mass. Gen. L. ch. 231, §85J, Plaintiffs are entitled to damages in treble the amount of damages sustained.

COUNT 9 – LOSS OF CONSORTIUM

208. Plaintiffs incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

209. At all times herein mentioned, Plaintiffs Gregory Zaff and Sonja Cantu were, and are, legally married as husband and wife.

210. As a direct and proximate result of the defective Profemur® Total Hip System and tortious conduct, and as a result of the injuries and damages to Plaintiff Gregory Zaff arising therefrom, Plaintiff Sonja Cantu has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations, and loss of physical assistance in the operation and maintenance of the home, of her husband, Gregory Zaff, and has thereby sustained and will continue to sustain damages.

211. Plaintiff Sonja Cantu is entitled to recover damages for her loss of consortium in an amount to be proven at trial.

COUNT X – LOSS OF CONSORTIUM

212. Plaintiffs Gregory Zaff and Zonja Cantu, as parents and next friends of their minor child, Kristina Zaff, repeat and incorporate by reference as if fully set forth herein the facts alleged in paragraphs 1-99 of this Complaint.

213. At all times relevant hereto, Plaintiffs were and are parents to their minor child, Kristina Zaff.

214. As a direct and proximate result of the defective Profemur® Total Hip System and tortious conduct, and as a result of the injuries and damages to Plaintiff Gregory Zaff arising therefrom, Kristina Zaff was caused to lose the care, comfort, society, companionship, services, guidance, counsel, support, consortium and advice of her father, Gregory Zaff, and has thereby sustained and will continue to sustain damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment and an award of damages against Defendants, as follows:

(a) for special damages, to include past and future medical and incidental expenses, according to proof;

(b) for past and future loss of earnings and/or earning capacity, according to proof;

(c) for past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

(d) loss of consortium;

(e) for pre-judgment and post-judgment interest;

(f) for the costs of this action, including reasonable attorneys' fees; and

(g) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

A TRIAL BY JURY IS RESPECTFULLY DEMANDED.

Respectfully submitted,

The Plaintiffs,
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